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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,752	11/21/2001	Darja Fercej Temeljotov	104101.B700017	5309

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
10/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/913,752	**Applicant(s)** FERCEJ TEMELJOTOV ET AL.	
	Examiner Kyle Purdy	**Art Unit** 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 04 October 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *3* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *71, 72, 76-82 and 84*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611

/Kyle Purdy/
Examiner, Art Unit 1611

Continuation of 11. does NOT place the application in condition for allowance because: Applicants arguments filed 3/11/2010 regarding the rejection of claims 71, 72, 76-82 and 84 made by the Examiner under 35 USC 103(a) over Akiyama et al. (WO 98/42311) in view of Al-Raxxak et al. (US 6010718) have been fully considered but they are not found persuasive and are MAINTAINED for the reasons of record.

In regards to the 103(a) rejection, Applicant asserts the following:

The Examiner has erroneously equated 'obvious to try' with obviousness under 103 because the courts have stated that throwing 'metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness' and that 'to explore' where the prior art gives only 'general guidance' results in impermissible 'obvious to try'. Akiyama teaches broad genera of compounds with broad genera of weight percentages. Akiyama provides a general teaching, but fails to provide Applicants particular form and how to achieve it; and

Al-Razzak does not remedy the deficiencies of Akiyama.

In response to A, Akiyama is directed to a gastrointestinal mucosa-adherent pharmaceutical composition which generically comprises a matrix of 1) an active agent; 2) a polyglycerol fatty acid ester; and 3) a viscogenic agent. While these groups themselves are extremely broad, Akiyama goes on to teach/suggest particular agents and amounts of those agents to be employed. With respect to the active agent, Akiyama suggests an active agent being that of a macrolide antibiotic such as clarithromycin. While no specific amount is taught for this specific agent, other prior art references (e.g. Al-Razzak) teach sustained release compositions having 500 mgs of clarithromycin to treat microbial infection (motivation). With respect to the inclusion of a polyglycerol fatty acid ester, this is obvious in view of Akiyama alone. Akiyama teaches Applicants glyceryl behenate, and suggests that it be included in the composition in an amount of from about 5-98% by weight, preferably about 20-95% by weight, and more preferably from 40-95% by weight (see column 7, lines 25-30). Not only does Akiyama provide a range which entirely encompasses Applicants range, Akiyama provides a percentage weight which directly reads on Applicants claimed range. If the art recognizes that a polyglycerol fatty acid ester can be used for a general purpose (e.g. glyceryl behenate) within a specific range or at given value, then any person would have had a reasonable expectation for success in their product/method, which uses a value within that range, being suitable for use in the field of endeavor of the prior art. With respect to the inclusion the viscogenic agent, Akiyama suggests hydropropylmethylcellulose (HPMC). The amount of viscogenic agent is taught at column 10, lines 5-10: "Referring to the amount of the viscogenic agent for use in the composition of the invention, its amount in the gastrointestinal mucosa-adherent matrix may for example be about 0.005 to about 99 weight %, preferably about 0.5 to about 45 weight %, more preferably about 1 to about 30 weight %, furthermore preferably about 1 to about 25 weight %, and for still better result, about 1 to about 20 weight %.' Thus, contrary to Applicants arguments, while Akiyama does provide a very broad range for the viscogenic agent (0.005-99%), it's taught that for the best results an amount from between 1-20% is to be used. Thus the Examiner contends that Akiyama as a whole is not equivalent to 'throwing metaphorical darts at a board filled with combinatorial prior art possibilities'. Rather, because Akiyama provides a general structure and preferred narrow means for achieving that structure, any ordinary person would have been capable of selecting and included Applicants claimed agents. Thus, their selection and inclusion would have been 'obvious to try'. Applicants arguments are not persuasive.

In response to B, while Akiymam teaches component weight percentages, Akiyama fails to teach including them in 'mg' amounts. Al-Razzak was cited to illustrate that Applicants claimed amount of HPMC and clarithromycin were known at the time the invention was made, and they would have been obvious to supplement in the teaching of Akiyama. Applicants argument is not persuasive. .